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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,660	01/25/2002	Karlheinz Bortlik	88265-6773	4348
28765	7590	03/22/2005		
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			EXAMINER DAVIS, RUTH A	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/057,660	BORTLIK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 January 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 65-76 and 78-93 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 65-76 and 78-93 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Applicant's response, amendment and election filed on January 3, 2005 has been received and entered into the case. Claims 1 – 21, 32 – 39 and 77 are canceled; claims 65 – 76 and 78 – 93 are added. Applicant's election of Group I is acknowledged. Since all pending claims are drawn to the elected invention, all claims have been considered. Claims 65 – 76 and 78 – 93 are pending and have been examined on the merits. All arguments have been fully considered.

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed at the EPO on May 30, 2000. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

It is noted, however, that while the instant application is a CIP of PCT application EP01/06145, no copy of PCT document EP01/06145 has been submitted.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 81, 82 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 81, 82 and 85 are drawn to a composition however are rendered vague and indefinite because it is unclear what composition is a percent of what. Specifically, it is unclear if the oral/cosmetic compositions comprise the claimed percents of the primary compositions, or if the primary composition comprise the claimed percents of another composition. For purposes of examination, the claims have been interpreted to mean the oral/cosmetic composition comprise the claimed percents of the primary composition.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 65 – 76 and 78 – 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz et al. (US 5643623).

Applicant claims a composition comprising at least one lipophilic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the

bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophilic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; the composition is a powder, gel or liquid; and the composition further comprises at least one of an emulsifier, stabilizer, or other additive. The LBC is 0.05 – 50% of the composition, the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, food supplement, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food; and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant additionally claims a composition with 0.001 – 100% or 10 – 50% of the claimed composition; as cosmetic comprising the composition which further comprises a compound active to the skin; and a cosmetic comprising 10<sup>^-10</sup> – 10% of the composition.

Schmitz teaches a human or animal food composition comprising 20 – 40% whey, 0.1 – 1% carotenoids, and 1.5 – 3.5% vitamin E and C (example 6). The antioxidant mixture may contain lycopene (abstract). Schmitz teaches the composition may be a solid, semi solid, liquid or gel (col.4 line 9-17). Specifically, Schmitz teaches a first component comprising 10 – 20% whey protein, 0.1 – 1% carotenoids, and 1.5 – 3.5% vitamin E and C (which are compounds

active with respect to skin) (example 6), wherein the first component further comprises a lipid carrier, herbal extract or mineral supplement (or additives) (col.5 line 23-28) and corn syrup (a sweetener) (example 6). Schmitz further teaches that the first component is blended such that the ingredients are dispersed and mixed together (examples) and that the first component is present in food products at 5 – 60% (col.5 line 55-60).

Although Schmitz does not teach the source from which the LBC were obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Schmitz does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

In addition, although Schmitz does not teach the claimed function of the whey, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new. Thus the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

Applicant argues that Schmitz does not teach a homogenous mixture of whey and LBC and that the reference does not teach the whey enhances bioavailability of the LBC.

However, these argument fail to persuade because as stated above, Schmitz clearly teaches a first component comprising whey and LBC that are mixed well together (or homogenized) (examples). Furthermore, it is reiterated that Schmitz teaches the claimed ingredients in the claimed amounts, thus the composition of Schmitz must inherently perform the functions as disclose by applicant. Otherwise applicant's invention could not function as claimed.

6. Claims 65 – 71, 73, 74 and 83 – 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al. (US 6203805 B1).

Applicant claims a composition comprising at least one lipophilic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophilic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the composition is a powder, gel or liquid; and the composition further comprises at least one of an emulsifier, stabilizer, or other additive. The composition is incorporated into a cosmetic which further comprises a compound active to the skin, and wherein the cosmetic comprises 10<sup>8</sup>-10 – 10% of the composition.

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Collins teaches cosmetic compositions comprising vitamins A, E and C (compounds active with respect to skin), and whey proteins (abstract). Collins teaches the composition in various cosmetic forms to include foundation (liquid), blush (powder), lipsticks or eyeshadow (gel) (col.5 line 23-33, col.6 line 42-46), and wherein the composition further comprises emollients (emulsifiers), preservatives (stabilizers) and other additives (col.6 line 42-55). The whey protein may be present at 50 – 10,000mcm/ml and the LBC (vitamins A, C, E) may be present at 1 – 100 mcm/ml, 20 – 200 mcm/ml, and about 800mcm/ml, respectively (col.4 line 52 – col.5 line 5, claims). Thus the cosmetic composition comprises about 0.6 – 1.08% of the whey/vitamin (or primary) composition.

Although Collins does not teach the source from which the LBC were obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

In addition, although Collins does not teach the claimed function of the whey, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new. Thus the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

Applicants argue that Collins does not teach the whey increases bioavailability of the LBC, but that the combination stimulates collagen synthesis, and that the amounts of whey in Collins is not enough to increase bioavailability of the LBC.

However, these arguments fail to persuade because Collins clearly teaches a primary composition comprising the claimed components in the claimed amounts. Therefore the composition of Collins must inherently perform the claimed functions as disclosed by applicant. Otherwise applicant's invention could not function as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis  
March 17, 2005  
AU 1651

A handwritten signature in black ink, appearing to read "Ruth A. Davis".